

Introduced by Senator Hill

January 6, 2014

An act to amend Section 14288 of, and to add Article 4.5 (commencing with Section 18770) to Chapter 4 of Part 3 of Division 9 of, the Food and Agricultural Code, relating to food and agriculture.

LEGISLATIVE COUNSEL'S DIGEST

SB 835, as amended, Hill. ~~Food-producing~~ *Food* animals: medically important antimicrobial drugs.

Under existing law, the Secretary of Food and Agriculture has the responsibility of ensuring that food products are not adulterated and that they are capable for use as human food. A violation of the laws and regulations relating to the adulteration of livestock or poultry products is a crime, punishable as specified. Existing law regulates the sale of livestock drugs by the secretary, and requires livestock drugs to be registered.

This bill would prohibit the secretary from registering a medically important antimicrobial drug, as defined, ~~for use on a food-producing animal~~, *which is administered to food animals, as defined, through feed or drinking water*, unless prescribed requirements are met. The bill would, *except as specified*, provide that a medically important antimicrobial drug currently registered with the department that does not meet the prescribed requirements has until January 1, 2017, to meet the prescribed requirements and reregister with the secretary. The bill would require a veterinarian-client-patient relationship, as described, to exist prior to the use of a medically important antimicrobial drug.

Because a violation of the bill's provisions would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 14288 of the Food and Agricultural Code
2 is amended to read:

3 14288. The secretary shall refuse to register a livestock drug
4 if he or she finds any of the following is true of the drug:

5 (a) It is of little or no value for the purpose for which it is
6 intended to be used.

7 (b) It is dangerous to the health of livestock if used in accordance
8 with the instructions.

9 (c) The instructions for use do not contain adequate warnings
10 against use in those conditions, whether pathological or normal,
11 under which its use may be dangerous to the health of livestock
12 or humans who consume products from the livestock, or against
13 unsafe dosage, unsafe duration of use, or unsafe methods of
14 administration.

15 (d) If the application and the accompanying material, data, and
16 information do not comply with the requirements of this chapter
17 or are insufficient to permit the secretary to make the
18 determinations that are required by this section.

19 (e) It is a medically important antimicrobial drug, as defined in
20 Section 18770, ~~for use in food-producing animals, which is~~
21 *administered to food animals, as defined in Section 4825.1 of the*
22 *Business and Professions Code, through feed or drinking water,*
23 unless the drug complies with Section 18771.

24 SEC. 2. Article 4.5 (commencing with Section 18770) is added
25 to Chapter 4 of Part 3 of Division 9 of the Food and Agricultural
26 Code, to read:

Article 4.5. Medically Important Antimicrobial Drugs

18770. For purposes of this article, the following definitions apply:

(a) “FDA” means the federal Food and Drug Administration.

(b) “Food animal” has the same meaning as defined in subdivision (c) of Section 4825.1 of the Business and Professions Code.

~~(b)~~

(c) “Medically important antimicrobial drug” means an antimicrobial drug listed in Appendix A of the FDA Guidance for Industry #152, including a critically important, highly important, and important antimicrobial drug. The secretary ~~may determine that shall have the discretion to consider any updates changes to~~ this list by the FDA ~~are also to determine whether a substance is~~ a medically important antimicrobial ~~drugs~~ drug.

(d) “Veterinary feed directive” is the directive described in Section 354 of Title 21 of the United States Code.

18771. To comply with FDA Guidance for Industry #213, dated December 2013, a medically important antimicrobial drug, including a combination drug incorporating a medically important ~~anti-microbial~~ antimicrobial drug, shall meet all of the requirements in the guidance document, including, but not limited to, the following:

(a) To reflect the need for professional oversight by a licensed veterinarian, the manufacturer shall remove from the approved production uses on the label of the medically important antimicrobial drug or combination drug the production indications, including, but not limited to, “increased rate of weight gain” or “improved feed efficiency.”

(b) The manufacturer shall revise the condition of the use of the medically important antimicrobial drug or combination drug from over the counter availability to a marketing status requiring veterinary prescription, including, but not limited to, the following:

(1) For medicated feed products, a change from over the counter to veterinary feed directive.

(2) For medicated drinking water products, a change from over the counter to veterinary prescription.

(c) ~~The~~ When administered through feed or drinking water the medically important antimicrobial drug may only be used to treat,

1 prevent, or control disease under the supervision of, or by
2 prescription from, a licensed veterinarian.

3 18772. There shall be a veterinarian-client-patient relationship
4 to ensure that a medically important antimicrobial drug is used in
5 a manner that is consistent with professionally accepted best
6 practices. For the purposes of this section, a
7 “veterinarian-client-patient relationship” is a relationship meeting
8 the requirements of Section 2032.1 of Title 16 of the California
9 Code of Regulations.

10 18773. (a) (1) If a medically important antimicrobial drug,
11 or combination drug, for use in ~~in food-producing~~ food animals is
12 registered with the department as of January 1, 2015, and the drug
13 does not comply with Section 18771, the manufacturer of the
14 medically important antimicrobial drug, or combination drug, shall
15 have until January 1, 2017, to reregister the drug with the secretary.
16 The secretary shall refuse to reregister the drug unless it complies
17 with Section 18771.

18 (2) *Notwithstanding paragraph (1), if a drug label reviewed by*
19 *the FDA under the Guidance for Industry #213 is delayed beyond*
20 *January 1, 2017, the secretary shall have the authority to continue*
21 *registering the drug during the FDA’s review period.*

22 (3) *If revision to the veterinary feed directive causes the FDA*
23 *to delay implementation of the Guidance for Industry #213, the*
24 *secretary shall have the authority to extend the time period by*
25 *which a manufacturer is required to reregister the drug pursuant*
26 *to paragraph (1) to be consistent with the delay in the*
27 *implementation of the guideline. If the secretary extends the time*
28 *period for reregistration, the extension shall not be later than the*
29 *federal implementation date of the guidance.*

30 (b) *If revisions to the veterinary feed directive causes the FDA*
31 *to revise the Guidance for Industry #213, the secretary shall have*
32 *the authority to promulgate regulations to ensure that California*
33 *law is consistent with the revisions to the guidance.*

34 SEC. 3. No reimbursement is required by this act pursuant to
35 Section 6 of Article XIII B of the California Constitution because
36 the only costs that may be incurred by a local agency or school
37 district will be incurred because this act creates a new crime or
38 infraction, eliminates a crime or infraction, or changes the penalty
39 for a crime or infraction, within the meaning of Section 17556 of
40 the Government Code, or changes the definition of a crime within

1 the meaning of Section 6 of Article XIII B of the California
2 Constitution.

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